



US006613319B2

(12) **United States Patent**  
**Leiden**(10) **Patent No.: US 6,613,319 B2**  
(45) **Date of Patent: \*Sep. 2, 2003**(54) **LONG-TERM EXPRESSION OF  
ERYTHROPOIETIN AND GROWTH  
HORMONE BY TRANSFORMING MUSCLE  
CELLS**(75) **Inventor: Jeffrey M. Leiden, Chicago, IL (US)**(73) **Assignee: Arch Development Corporation,  
Chicago, IL (US)**(\*) **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.: 09/091,134**(22) **Filed: Jun. 23, 1998**(65) **Prior Publication Data**

US 2002/0122788 A1 Sep. 5, 2002

**Related U.S. Application Data**(60) **Provisional application No. 60/024,511, filed on Aug. 23, 1996.**(51) **Int. Cl.<sup>7</sup> ..... A01N 63/00; A01N 43/04;  
A61K 48/00; A61K 31/70; C12N 15/63**(52) **U.S. Cl. .... 424/93.2; 424/93.1; 424/93.21;  
424/93.6; 424/93.7; 435/320.1; 435/455;  
514/44**(58) **Field of Search ..... 424/93.1, 93.2,  
424/93.21, 93.6, 93.7; 435/320.1, 455;  
514/44**(56) **References Cited****U.S. PATENT DOCUMENTS**5,580,859 A 12/1996 Felgner et al. .... 514/44  
5,693,622 A 12/1997 Wolff et al. .... 514/44  
5,858,351 A 1/1999 Podsakoff et al. .... 424/93.2**FOREIGN PATENT DOCUMENTS**

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(List continued on next page.)

**Primary Examiner—Anne-Marie Falk**(74) **Attorney, Agent, or Firm—Hale and Dorr LLP**(57) **ABSTRACT**

A process for increasing the circulating levels of gene products in a primate for extended period of time is provided. In accordance with that process, muscle cells of the mammal are transformed with an expression vector that contains a polynucleotide that encodes the gene product and which vector drives expression in the muscle.

**24 Claims, No Drawings**